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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,128	11/27/2001	Alan N. Houghton	MSK.P-026-3	3698

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,128	HOUGHTON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *3,6-9,13-16,18 and 25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,10-12 and 19-23* is/are rejected.

7)☒ Claim(s) *17 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/05/02, 03/07/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Claims 1-27 are pending.

Claims 3, 6-9, 13-16, 18 and 25-27, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 2, 4, 5, 10-12, 17 and 19-24 are examined on the merits to the extent that the xenogeneic differentiation antigen is a human tyrosinase.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The instant application properly reflects the current status of the parent application in the first line of the specification.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 2, 4, 5, 10, 11 and 19-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' arguments.

5. The provisional rejection of claims 17 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13 and 16-19 of copending Application No. 10/041,410 (filed January 7, 2002) is withdrawn.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1, 2, 4, 5, 10-12, 19-23 under 35 U.S.C. 103(a) as being unpatentable over Disis et al. (The Journal of Immunology 156: 3151-3158, May 1, 1996), and further in view of Naftzger et al. (Proc. Natl. Acad. Sci. USA 93: 14809-14814, December 1996/ IDS reference on page 2 submitted March 5, 2002) is withdrawn in light of Applicants' arguments.

New Grounds of Rejection and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claims 1, 4, 10, 11, 19, 20 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating canine melanoma comprising the step of administering to an immunologically-effective amount of a xenogeneic differentiation antigen, human tyrosinase, does not reasonably provide enablement for the broad treatment of melanoma in a mammalian subject comprising the step of administering the broad class of xenogeneic differentiation antigens. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants have provided Example 8 on pages 11-13 exemplifying melanoma treatment of dogs using xenogeneic tyrosinase differentiation antigen. Applicants are not enabled for the treatments of melanoma in any mammal wit the broadly identified xenogeneic differentiation antigen as listed in claims 1, 4, 10, 11, 19, 20 and 23. These claims require a therapeutically effective amount of nucleic acids encoding differentiation antigens to be delivered in vivo to a mammal in need of melanoma treatment. It is noted that the claims encompass a genus of differentiation antigens, which according to the specification are "...tissue-specific antigens that are shared by autologous and some allogeneic tumors of similar derivation, and [also] on normal tissue counterparts at the same stage of differentiation, see page 1, lines 5-7. The definition does not aid in clarifying or limiting this broad group. The specification provides guidance as to how to target the administered human tyrosinase nucleic acids to the non-human dog subjects. However, the instant specification does not teach how to overcome problems with *in vivo* delivery and expression with respect to the broad genus of differentiation antigen as claimed. The state of the art regarding in vivo delivery of nucleic acids is highly unpredictable. For instance, Eck et al (Gene Based Therapy in The Pharmacological Basis of Therapeutics, Goodman and Gilman, Eds, 1996, pp. 77-101) teach that the fate of the DNA vector itself with regard to the volume of distribution, rate of clearance into tissues etc., the *in vivo* consequences of altered gene expression within cells which are expressing the gene, the fraction of vector taken

up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the nucleic acid, the level of mRNA produced, the stability of the mRNA produced in vivo, the amount and stability of the protein produced and the proteins compartmentalization or secretory fate within the cell are primary considerations regarding effective therapy. Eck states that these factors differ dramatically with respect to the vector used, the protein being produced, and the disease being treated (Eck et al bridging pages 81-82). The specification does not teach the broadly claimed method in the context of implementing a genus of xenogeneic differentiation antigens in melanoma treatment. Given the lack of guidance from the specification one of ordinary skill in the art would be subject to undue experimentation without reasonable expectation of success to practice the broadly state method of treatment.

Double Patenting

8. The provisional rejection of claims 1, 2, 4, 5, 10-12 and 19-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 11-13 and 16-19 of copending Application No. 10/041,410 (filed January 7, 2002) is maintained.

Allowable Subject Matter

9. Claims 17 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Claims 1, 2, 4, 5, 10-12, 17 and 19-24 are free of the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
18 April 2005